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PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:

Fallaux et al.

Serial No.: 10/618,526

Filed: July 11, 2003

For: PACKAGING SYSTEMS FOR
HUMAN RECOMBINANT ADENOVIRUS
TO BE USED IN GENE THERAPY

Confirmation No.: 5055

Examiner: S. Priebe, Ph.D.

Group Art Unit: 1633

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BRIEF ON APPEAL

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P.O. Box 1450
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Attention: Board of Patent Appeals and Interferences

Sirs:

This Appeal Brief is submitted in the format required by 37 C.F.R. § 41.37 and with the fee required by 37 C.F.R. § 41.20(b)(2).

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I. REAL PARTY IN INTEREST

U.S. Application Serial No. 10/618,526 (hereinafter "the '526 Application"), the application at issue, has been assigned to Crucell Holland B. V., as evidenced by the assignment that has been recorded with the U.S. Patent and Trademark Office ("USPTO") at Reel No. 017353, Frame No. 0358. Accordingly, Crucell Holland B.V. is the real party in interest.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellant or their representatives related to the pending appeal that will directly affect, be directly affected by, or otherwise have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1, 3-7, 10, 11, 16, and 21-25 are currently pending in the above-referenced patent application. Claims 1, 3-7, 10, 11, 16, 21-22, and 25 stand rejected under the judicially created doctrine of obviousness-type double patenting (ODP). Claims 23 and 24 have been allowed. Claims 2, 8, 9, 12-15, and 17-20 have been cancelled. The ODP rejections of claims 1, 3-7, 10, 11, 16, 21, 22, and 25 are being appealed.

IV. STATUS OF AMENDMENTS

The claims of the '526 Application were last revised in an Amendment dated March 2, 2007. The claims, as revised, were then considered by the Examiner, as indicated by the final Office Action of March 27, 2007. A terminal disclaimer was deposited with the USPTO on April 27, 2007 and recorded on May 18, 2007.

V. SUMMARY OF CLAIMED SUBJECT MATTER

This appeal involves legal issues that are independent of the subject matter defined by the claims on appeal. In conformance with the requirements of M.P.E.P. § 1205, however, Appellant summarizes the claimed subject matter as follows: An isolated adenovirus packaging cell comprising in its genome a first nucleic acid sequence encoding adenovirus E1A and E1B gene products but lacking a nucleic acid sequence encoding adenovirus pIX. See As filed

specification, page 21, lines 8-17; page 24, lines 6-7, 23-26; page 25, lines 8-11; page 26, lines 1-4; Figs. 4A-4B.

In certain embodiments, the packaging cell further includes a recombinant expression vector derived from a human adenovirus genome, wherein the recombinant expression vector comprises an adenovirus gene encoding a pIX protein, but lacks nucleic acid sequences that overlap with said first nucleic acid sequence, and further wherein the recombinant expression vector is IG.Ad.MLPI.TK shown in FIG. 12. See As filed specification, page 21, lines 8-17; page 24, lines 6-7, 23-26; page 25, lines 8-11; page 26, lines 1-4; Figs. 4A-4B; page 9, lines 13-18; page 26, lines 7-23; page 27, lines 1-22; FIGS. 11A, 11B, and 12. In other embodiments, the recombinant expression vector is derived from a human adenovirus 5 genome from which nucleotides 459-3510 have been deleted. See As filed specification, page 21, lines 8-17; page 24, lines 6-7, 23-26; page 25, lines 8-11; page 26, lines 1-4; Figs. 4A-4B; page 9, lines 13-18; page 26, lines 7-23; page 27, lines 1-18; FIGS. 11A, 11B.

VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1, 3-7, 10, 11, 16, 22, and 25 stand rejected over the judicially created doctrine of obviousness-type double patenting (ODP) over claims 43 and 44 of U.S. Patent No. 6,340,595 and claims 7, 32, and 35 of U.S. Patent No. 6,413,776.

Claims 1, 3-7, 16, 21, and 25 stand rejected over the judicially created doctrine of obviousness-type double patenting (ODP) over claims 67 and 95 of U.S. Patent No. 7,029,848.

U.S. Patent Nos. 6,340,595, 6,413,776, and 7,029,848 are referred to collectively as the "reference patents" hereinafter.

VII. ARGUMENT

The factual background of this appeal involves the prosecution of multiple related applications with overlapping inventorship and different ownership. The issues presented for consideration by this Board, however, involve primarily the following salient facts, each of which is believed to be non-controversial:

1. The effective priority date of the claims on appeal is June 15, 1995, (the filing date of European Patent Application EP 95201611.1) which fully discloses the inventions defined by these claims).

2. The normal statutory expiration date of the claims on appeal is June 14, 2016, twenty years from filling of PCT/NL96/00244 (WO 97/00326), subject to any term extensions available under 35 U.S.C. § 154(b).

3. A terminal disclaimer of any term extension of the claims on appeal beyond June 14, 2016 is of record.

4. The statutory expiration date of each of the reference patents is subsequent to June 14, 2016; that is, there is no possibility of a disfavored term extension of any reference patent claim as a consequence of the issuance of the claims on appeal.

5. The reference claims and the claims on appeal share a common inventor, but are assigned to different entities. Additionally, the reference claims and the claims on appeal did not result from activities undertaken within the scope of a joint research agreement; therefore, 37 C.F.R. § 1.321(d) is not applicable.

6. The claims on appeal are acknowledged to define different inventions than those defined by the reference claims. The ODP rejections at issue are based upon a one-way analysis; (the reference patent claims are acknowledged to be patentable over the claims on appeal).

7. The ODP rejections at issue are based upon the analysis illustrated by Chart II-B of M.P.E.P. § 804.

A. APPLICABLE LAW

The law applicable to the issues relevant to this appeal includes the decisional law pertaining to non-statutory double patenting rejections; more commonly denominated “the judicially created obviousness-type double patenting (ODP) rejection.” Controlling precedent for this Board is limited to decisions of the Supreme Court, *en banc* decisions of the Court of Appeals of the Federal Circuit, decisions by the Federal Circuit, or its predecessors, which the Federal Circuit considers binding precedent, and decisions of this Board that by their terms specify that they are to be treated as precedential by future panels of the Board. Memorandum from Michael R. Fleming, Chief Admin. Patent Judge, to Admin. Patent Judges, Standard

Operating Procedure 2 (Revision 6) (Aug. 10, 2005), *available at* <http://www.uspto.gov/web/offices/dcom/bpai/sop2.pdf>.

The USPTO is authorized to establish regulations not inconsistent with law for the conduct of proceedings in the USPTO. 35 U.S.C. § 2. These rules govern the examiners, as well as applicants and their representatives. The examining corps is bound to implement the rules in accordance with instructions set forth in the M.P.E.P. However, the Board is not *per se* bound by the M.P.E.P. Santarsiero v. Delucas, 2006 WL 180720, *6 n.6 (B.P.A.I May 31, 2006) (“At any rate, we are not bound by the M.P.E.P. which, while giving an indication of ‘presumptions under which the PTO operates,’ does not have the force of law.” (quoting Critikon Inc. v. Beckton Dickenson Vascular Access, Inc., 120 F. 3d 1253, 1257 (Fed. Cir. 1997))).

B. REFERENCES RELIED UPON

The references relied upon are: claims 43 and 44 of U.S. Patent No. 6,340,595, claims 7, 32 and 35 of U.S. Patent No. 6,413,776, and claims 67 and 95 of U.S. Patent No. 7,029,848. This appeal raises no art-related issues with respect to the references.

C. ANALYSIS

This appeal is from rejections based upon the judicially created obviousness-type double patenting (ODP) doctrine. It stems from a putatively good faith application by the examining corps of the analysis articulated at M.P.E.P. § 804. The rejections improperly apply a “one-way” patentability test (addressed subsequently in this brief). Apart from that fundamental error, Appellant acknowledges that the final rejections can be viewed as being in literal harmony with Chart II-B of § 804. Nevertheless, they are out of harmony with current USPTO policy, as reflected by the textual explanation of 37 C.F.R. § 1.321(c) found in M.P.E.P. §§ 804 and 1490. In particular, the requirement of 37 C.F.R. § 1.321(c)(3), pertaining to terminal disclaimers filed to overcome ODP rejections, cannot fairly be applied to applicants who have no ownership interest in the reference patent. Such applicants, including this appellant, lack the capacity to comply. Therefore, 37 C.F.R. § 1.321(b) is the operable rule in this case, and the terminal disclaimer accepted by the USPTO on May 18, 2007 is sufficient to obviate the ODP rejection at issue in this appeal. The guidelines of Chart II-B, as applied to Appellant, are unjustifiably

prejudicial. They are not mandated by any authority controlling on this Board. It is error to regard the potential for harassment by multiple owners of patents having a common inventor as sufficient basis, standing alone, for an ODP rejection. The ODP rejection is especially egregious where, as here, the claims define patentably distinct inventions. This Board has the authority to correct current ODP practice, and should do so to avoid unequal protection of similarly situated patentees.

The double patenting rejection, let alone the ODP extension of this doctrine, has never been codified in the patent statutes. 37 C.F.R. § 1.321 and M.P.E.P. § 804.02 VI mandate the requirement for a terminal disclaimer to overcome an ODP rejection. Two justifications are offered for this mandate: (1) 35 U.S.C. § 154(b) provides for term extensions based upon prosecution delays, thereby potentially extending the nominal 20 year term to a date later than the expiration date of a reference patent claim; and (2) 37 C.F.R. § 1.321(c)(3) provides that terminal disclaimers filed to overcome ODP rejections include a provision that any patent granted on the rejected application be enforceable only during the period that it is commonly owned with the reference application. M.P.E.P. § 804.02 VI.

37 C.F.R. § 1.321(c)(3) is not properly applicable under the circumstances of this case. M.P.E.P. § 804.02(VI) states, “37 C.F.R. § 1.321(c)(3) requires that a terminal disclaimer filed to obviate a nonstatutory double patenting rejection **based on commonly owned conflicting claims** include a provision that any patent granted on that application be enforceable only for and during the period that the patent is commonly owned with the application or patent which formed the basis for the rejection.” M.P.E.P. § 1490(V)(A) states, “A terminal disclaimer filed to obviate a nonstatutory double patenting rejection **based on a commonly owned patent or application** must comply with the requirements of 37 C.F.R. § 1.321(c).” These directives strongly imply that the USPTO regards 37 C.F.R. § 1.321(c) as applying only to ODP rejections involving common ownership. The ODP rejections at bar acknowledge the absence of common ownership.

Chart II-B of M.P.E.P. § 804 does not, by its terms, actually require the final ODP rejections at issue. This chart is putatively intended to offer instruction to the examiners concerning applicable standard paragraphs for inclusion in office actions. Specifically, when an examiner is confronted with a factual circumstance in which there are “conflicting” claims

between an application and a patent, there is at least one common inventor and no common assignee; the chart directs the use of standard paragraphs 8.33 and either 8.34 or 8.36 (inapplicable in this case.) Paragraph 8.33 specifies, in pertinent part: “A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) . . . may be used to overcome [a] . . . rejection based on a nonstatutory double patenting ground provided the conflicting . . . patent is shown to be commonly owned with this application.” Paragraph 8.33 is, by its terms, permissive. If an applicant is in a position to show common ownership, it can take advantage of the tailored procedure specified by 37 C.F.R. § 1.321(c). However, if an applicant cannot show common ownership because there is none, it is implicit that the applicant can file a terminal disclaimer in accordance with 37 C.F.R. § 1.321(b), as both case law and the M.P.E.P. clearly state that a rejection based on a nonstatutory type double patenting can be avoided by filing a terminal disclaimer, without specific regard to common ownership. In re Vogel, 422 F.2d 438, 441-42 (CCPA 1970); In re Knohl, 386 F.2d 476 (CCPA 1967); In re Griswold, 365 F.2d 834 (CCPA 1966); M.P.E.P. § 804.02(II). Appellant has done so. The rejections are thereby avoided.

In the instant case, a terminal disclaimer has been filed pursuant to 35 USC § 253, as a matter of right. The terminal disclaimer precludes any extension beyond the normal 20-year term. It should thus obviate any concern raised by 35 U.S.C. § 154(b), without regard to any issue of common ownership. This disclaimer should not be considered through the prism of 37 C.F.R. § 1.321(c); it does not, and is not intended to comply with that portion of the rule. Rather it should be considered as being in full compliance with 37 C.F.R. § 1.321(b), which harmonizes with 35 U.S.C. § 253, as it applies to applicants generally.

37 C.F.R. § 1.321 acknowledges, *inter alia*, the right of an applicant to file a terminal disclaimer. Section (b) specifies the requirements for a terminal disclaimer to be recordable at the USPTO. Section (c) specifies an additional recording requirement in the case of a terminal disclaimer filed specifically to obviate a nonstatutory double patenting rejection (based upon common ownership, per M.P.E.P. §§ 804 and 1490). In the case at hand, Appellant has met the requirements for filing a recordable terminal disclaimer, thereby avoiding any potential for a disfavored term extension.

37 C.F.R. § 1.321(c) cannot rationally be applicable in the absence of common ownership. Otherwise, Appellant is placed in an unwarranted “catch 22” situation, being both

required and forbidden to assert an ownership interest in the reference patent claims. To impose the “common ownership” requirement of section (c) under the facts of this case prejudices Appellant in comparison with others similarly situated. It constitutes a classic example of honoring form over substance — particularly inappropriate in this case where the dominant “form” has no statutory or other properly controlling basis.

As is very often the case, the claims on appeal dominate narrower claims owned by another party. More specifically, the methods of the reference claims have been found inherently to disclose the packaging cell defined by the dominant claim. Significantly, the reference claims are supported by disclosure that is not available as a reference. The reference claims are applied as prior art only because of the incidental overlapping inventorship that exists; otherwise, the rejected claims would presumably issue in a second patent. The unrelated patentee would then have all of the rights currently being denied to Appellant with respect to the claims on appeal. As a matter of public policy, there can be no justification for singling out Appellant for special, disadvantageous, treatment after term extension issues have been resolved.

The fundamental reason for the rule against double patenting is *to prevent unjustified time-wise extension of the right to exclude granted by a patent*. In re Van Ornum, 686 F.2d 937, 943-44 (C.C.P.A. 1982). Appellant acknowledges that this fundamental justification has sometimes been buttressed by a secondary policy consideration — to avoid potential harassment by multiple assignees. Id. at 944-48. This secondary consideration, however, cannot reasonably stand alone as justification for an ODP rejection. The perceived evil of “harassment” is scarcely touched by the ODP practice represented by the rejections in this case. *A priori*, anyone making, using, selling, or offering for sale any “new” commodity, method, or item of manufacture runs the risk of being sued for the infringement of multiple patents. Apart from term extension issues, no longer present in this case, an accused infringer is in no way disadvantaged by the existence of a common inventor of variously owned patents. Multiple patents may or may not lead to “harassment,” under any number of speculative scenarios. The existence of harassment is a question of fact, which has no apparent direct connection to either common inventorship or common ownership. The USPTO is not well positioned to deal with harassment in fact. Should harassment actually arise in a litigation context, the trial judges are well equipped to protect a party subjected to such harassment and to sanction a party responsible for such harassment.

Considering the existence of a common inventor to constitute *de facto* harassment for purposes of justifying an ODP rejection, (particularly when that rejection stems from a one-way obviousness determination), is manifestly unreasonable. No statutory or decisional law mandates such an analysis.

If the subject matter of the unrelated reference patents were invented by another inventive entity, an ODP rejection would not be proper under current USPTO practice. In this case, the Examiner has acknowledged that the claims of the reference patents are non-obvious in light of the present application. Office Action mailed on 3/1/2006, page 5. The present application could have issued prior to the filing of the reference patents, (the disclosure of the present application was published over a year prior to the filing of the reference patents). The claims of the reference patents would presumably have issued, and any potential infringer would be subject to suit by both the owner of the reference patents and the owner of the present application. That reality cannot reasonably be regarded as *de facto* "harassment." There is no logical basis for assuming a higher harassment level based solely on overlapping inventorship.

A terminal disclaimer conforming to the requirements of 37 C.F.R. § 1.321(c) would overcome an ODP rejection under circumstances in which the rejected and reference claims were commonly owned, but the rejected claims were licensed, either exclusively or non-exclusively, to a related or unrelated party. In theory, if Appellant could obtain an assignment of the reference patents, it could grant back exclusive licenses to the original owners, but avoid the ODP rejections by filing a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c). This procedure would exalt form over substance to approximately the same degree as do the ODP rejections at issue. Nevertheless, its availability is illustrative of the absurdity of extending the requirements of 37 C.F.R. § 1.321(c) beyond the special circumstances presented by commonly owned reference and rejected patent claims.

In re Van Ornum, 686 F.2d 937 (C.C.P.A. 1982) involved an attack upon the validity of the provision now found in 37 C.F.R. § 1.321(c). In that case, the United States Court of Customs and Patent Appeals held that the provision was valid and upheld an ODP rejection under circumstances in which a terminal disclaimer was deemed insufficient. Id. at 939. By contrast, this appeal does not attack the validity of section 1.321(c), only its applicability to the facts at hand. The Van Ornum decision has admittedly been construed in cases lacking any

precedential authority as standing for the proposition that, even without the possibility of a timewise extension of a patent, an ODP rejection is proper and indeed required to avoid theoretical harassment by multiple patentees. *See e.g., Ex parte Heung*, App. No. 1998-0346, 2003 WL 23014585, at *2 (B.P.A.I 2003) (non-precedential opinion). The Van Ornum decision does not in fact stand for such a proposition. The Federal Circuit apparently favors a case-by-case determination of whether an ODP rejection is proper, even under circumstances in which a time extension results. *See In re Braat*, 937 F.2d 589, 594 (Fed. Cir. 1991). The Board, in Ex parte Heung, adopted a much different understanding of the Van Ornum decision than is reflected by the Federal Circuit in its In re Braat decision. The Federal Circuit recognized that even though Van Ornum states that “‘the fundamental reason for the rule [against “double patenting”] is to prevent unjustified timewise extension of the right to exclude no matter how the extension is brought about’, . . . there are situations where the extension is justified.” In re Braat, at 595. It follows that if an ODP rejection is not always proper even when there is a timewise extension of the right to exclude; ODP rejections must not be always proper, (perhaps never proper), when there is no patent extension and only the theoretical possibility of harassment by multiple assignees. The equities weigh heavily against an ODP rejection in this case because Appellant is not in a position to comply with 37 C.F.R. § 1.321(c)

The one-way patentability test applied in this case was improper

A two-way obviousness test is to be applied when the applicant could not have filed the claims in a single application, In re Berg, 140 F.3d 1428, 1434 (Fed. Cir. 1998), and, “where, through no fault of the applicant, the claims in a later filed application issue first.” M.P.E.P. § 804(B)(1)(b) (citing In re Braat, 937 F.2d 589 (Fed. Cir. 1991)). In this case, the Examiner has acknowledged that the first prong of the test has been met; the claims on appeal could not have been filed with the reference claims. Office Action mailed on 3/1/2006, page 8. The issue before this Board is whether the second prong has also been met in this case.

The Examiner asserts that the second prong cannot be met in the present case because the present application was filed after the issuance of the ‘595 and ‘766 patents and therefore any delay was the fault of the applicant. Id. at 9. That conclusion is contrary to Federal Circuit precedent. The facts of the present case are strikingly parallel to the facts of In re Braat. In that

case, the Federal Circuit found a two-way obviousness test appropriate under the very same circumstance relied upon for disqualification of the two-way test in this case. Braat filed an application on January 10, 1984, based upon an application filed on July 17, 1978, which in turn claimed priority from a Netherlands patent application filed April 3, 1978. In re Braat, at 590. The Braat application disclosed an invention, which was expanded upon in some embodiments of an invention that issued in a patent to Dil. Id. at 591, 593-94. In fact, the Dil patent specifically cited to the parent application of the Braat application. Id. The Dil patent issued June 24, 1980, on an application filed January 31, 1979. Id. at 590.

The Federal Circuit stated that an applicant, who files applications for basic and improvement patents should not be penalized by the rate of progress of the applications through the USPTO, a matter over which the applicant does not have complete control. Id. at 593. Based on these facts the Federal Circuit held that a two-way obviousness test was appropriate “[i]t is not Philips' fault that the combination claims in the Dil patent issued first.” Id. at 594. Thus, the Federal Circuit held it was not applicant's fault that the Dil patent issued before the Braat patent **despite the fact that the Braat patent was filed on January 10, 1984, which was three and a half years after the Dil patent issued on June 24, 1980.** The Federal Circuit noted that the Dil patent used the invention disclosed by the parent of the Braat application, and determined that it would be unfair to then not allow the Braat application to issue based on an application that used its invention.

The factual setting of this case is nearly identical to that considered by the Federal Circuit in In re Braat. The present application was filed on July 11, 2003, based on an application filed on June 14, 1996, which in turn claimed priority from a European application filed on June 15, 1995. The present application discloses an invention, PER.C6 cells, which was used in separate inventions filed in applications in July 1999 and June 1998, which issued as the '595 and '776 patents in January and July of 2002, respectively. Just as the Dil patent made reference to the Braat application, the '595 and '776 patents specifically cite to the parent application of the present application. The ODP rejection at issue, being based upon a one-way patentability test, ignores the precedent of In re Braat. The claims on appeal are entitled to a two-way obviousness test as a matter of law. The ODP rejections are thus improper, and should be reversed by this Board.

VIII. CLAIMS APPENDIX

The current status of each claim that has been introduced into the above-referenced application is set forth in CLAIMS APPENDIX to this Appeal Brief.

IX. EVIDENCE APPENDIX

No evidence has been submitted pursuant to 37 C.F.R. § §§ 1.130, 1.131, or 1.132. Accordingly, no evidence appendix accompanies this Appeal Brief.

X. RELATED PROCEEDINGS APPENDIX

No decisions have been rendered by the board or any court in a related application. Therefore, a related proceedings appendix does not accompany this Appeal Brief.

XI. CONCLUSION

The ODP rejections of claims 1, 3-7, 10, 11, 16, 21-22, and 25 should be reversed, and each of these claims should be allowed.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "David V. Trask", followed by the text "Reg No. 33,041".Handwritten initials "DVT" in black ink.

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Document in ProLaw



Serial No. 10/618,526

CLAIMS APPENDIX

1. An isolated adenovirus packaging cell comprising in its genome:
a first nucleic acid sequence encoding adenovirus E1A and E1B gene products but lacking a nucleic acid sequence encoding adenovirus pIX.
3. The isolated adenovirus packaging cell of claim 1, wherein said first nucleic acid sequence comprises nucleotides 459-3510 of the human adenovirus 5 genome.
4. The isolated adenovirus packaging cell of claim 1, wherein the isolated adenovirus packaging cell is of a retina cell origin.
5. The isolated adenovirus packaging cell of claim 1, wherein the isolated adenovirus packaging cell is of a primary cell origin.
6. The isolated adenovirus packaging cell of claim 1, wherein the isolated adenovirus packaging cell is of an embryonal cell origin.
7. The isolated adenovirus packaging cell of claim 1, wherein the isolated adenovirus packaging cell is a human cell.
10. The isolated adenovirus packaging cell of claim 1, further comprising a nucleic acid sequence encoding an adenovirus E2A gene product.
11. The isolated adenovirus packaging cell of claim 10, wherein the adenovirus E2A gene product includes a temperature sensitive 125 mutation.
16. The isolated adenovirus packaging cell of claim 1, wherein the isolated adenovirus packaging cell is of human embryonic retinoblast (HER) origin.

21. The isolated adenovirus packaging cell of claim 1, further comprising a recombinant expression vector derived from a human adenovirus genome, wherein said expression vector comprises an adenovirus gene encoding a pIX protein and further wherein said expression vector lacks nucleic acid sequences that overlap with said first nucleic acid sequence.

22. The isolated adenovirus packaging cell of claim 10, wherein the nucleic acid sequence encoding an adenovirus E2A protein is operatively linked to an E1A-independent transcription initiation region.

23. An isolated adenovirus packaging cell, comprising, in its genome,
a first nucleic acid sequence encoding adenovirus E1A and E1B gene products, but lacking a nucleic acid sequence encoding adenovirus pIX, and
a recombinant expression vector derived from a human adenovirus genome, wherein said recombinant expression vector comprises an adenovirus gene encoding a pIX protein, but lacks nucleic acid sequences that overlap with said first nucleic acid sequence, and further wherein the recombinant expression vector is IG.Ad.MLPI.TK shown in FIG. 12.

24. An isolated adenovirus packaging cell, comprising, in its genome,
a first nucleic acid sequence encoding adenovirus E1A and E1B gene products, but lacking a nucleic acid sequence encoding adenovirus pIX, and
a recombinant expression vector derived from a human adenovirus genome, wherein said recombinant expression vector comprises an adenovirus gene encoding a pIX protein, but lacks nucleic acid sequences that overlap with said first nucleic acid sequence, and further wherein the recombinant expression vector is derived from a human adenovirus 5 genome from which nucleotides 459-3510 have been deleted.

25. The isolated adenovirus packaging cell of claim 1, wherein the first nucleic acid sequence encodes adenovirus E1A, E1B 21 kDa and E1B 55 kDa gene products.